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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/697,068 | 10/30/2003 | Brian Burkinshaw | 2108.000400/IOI-444-CIP | 8117 |
| 45488 | 7590 | 03/20/2006 | EXAMINER | |
| WILLIAMS, MORGAN & AMERSON | | | REIMERS, ANNETTE R | |
| 10333 RICHMOND, SUITE 1100 | | | ART UNIT | |
| HOUSTON, TX 77042 | | | PAPER NUMBER | |

3733

DATE MAILED: 03/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/697,068

Applicant(s)

BURKINSHAW ET AL.

Examiner

Annette R. Reimers

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) 4-8, 10, 11, 15-31, 33, 42-44, 46, 51, 55, 56 and 58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 9, 12-14, 32, 34-41, 45, 47-50, 52-54, 57 and 59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 9, 12-14, 32, 34-41, 45, 47-48, 52-54, 57 and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by Garretson (U.S. Patent No. 3,835,860).

Garretson discloses a device for forming multiple holes in subchondral bone, comprising a housing, 12, coupled to a fracture pin having a sharpened tip, 38 and 39, the sharpened tip adapted to penetrate subchondral bone, and a trigger, 27, that is adapted to, when actuated, cause the sharpened tip to move and penetrate into the subchondral bone, thereby forming at least one of the holes.

A biasing member is adapted to cause the sharpened tip to return to an initial, retracted position after the hole has been formed (see column 5, lines 1-7). The trigger has a biasing spring, 124, coupled to the trigger such that when the trigger is actuated, a biasing force is created to return the trigger to an initial starting position (see column 4, lines 35-36). The device further discloses a guide tube, 22, with an angled tip, 52, wherein the fracture pin is positioned within the guide tube. A means is provided for

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limiting the movement of the sharpened tip when the trigger is actuated to limit the depth of the hole (see column 2, lines 1-9).

The device also includes a moveable hammer, 150, coupled to the trigger, that when actuated, causes the sharpened tip to move and penetrate into the subchondral bone forming a hole. The hammer is coupled to a biasing member, 162, the biasing member being adapted to create a bias force when the hammer is rotatably moved by actuation of the trigger. A recess, 153, is formed in the hammer and a structural member, 154, coupled to the trigger, in which a portion of the structural member is positioned in the recess in the hammer. The structural member comprises a sliding removable cross bar, and the cross bar is adapted to be positioned in the recess in the hammer (see figure 5).

It is noted that the preamble of claims 1, 32 and 54 recites "A device for forming multiple holes in subchondral bone" which amounts to an intended use recitation. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garretson (U.S. Patent No. 3,835,860).

Garretson discloses the claimed invention except for the device wherein the angled tip has an angle that ranges from approximately 30-60 degrees and wherein the guide tube has an outside diameter that ranges from approximately 6-8 millimeters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Garretson wherein the angled tip has an angle that ranges from approximately 30-60 degrees and wherein the guide tube has an outside diameter that ranges from approximately 6-8 millimeters, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Response to Arguments

Applicant's arguments filed December 27, 2005 have been fully considered, but they are not persuasive. Applicant believes that the bone punch device of Garretson is not adapted for forming multiple holes in subchondral bone. Applicant is reminded that with regard to the statement of intended use and other functional statements, they do

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not impose any structural limitations on the claims distinguishable over Garretson, which is capable of being used as claimed if one so desires to do so. In re Casey, 152 USPQ 235 (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. Kalman v. Kimberly Clark Corp., 218 USPQ 781 (CCPA 1983). Moreover, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural not functional limitations Ex parte Masham, 2 USPQ2d 1647 (1987) (emphasis added).

The examiner maintains that the bone punch device of Garretson is capable of being used to form multiple holes in subchondral bone, unless applicant can show otherwise. It is the burden of the applicant to provide enough details to prove that the structure disclosed by Garretson is incapable of performing the claimed functions. Again, applicant's argument that the device of Garretson does not include certain features of applicant's invention, the limitations on which the Applicant relies (i.e., "The purpose of such holes is to induce fibrin clot formation and migration of primitive stem cells from the bone marrow into defective cartilage locations, to induce bleeding from the holes, and to release fat droplets from the holes") are not stated in the claims. Therefore, it is irrelevant whether the reference includes those features or not. Furthermore, the bone punch device of Garretson meets all of the structural limitation set forth in the claims.

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Applicant's arguments with regard to claims 49 and 50 do not overcome the rejections applied thereto, since applicant has not provide any convincing showing that these are nothing more than optimum or workable values as asserted by the examiner. Applicant has not provided any showing that such limitations are "critical". In re Cole, 140 USPQ 230 (CCPA 1964); In re Kuhle, 188 USPQ 7 (CCPA 1975); In re Davies, 177 USPQ 381 (CCPA 1973). Mere arguments by counsel cannot take the place of evidence. In re Cole, 236 F.2d 769, 773, 140 USPQ 230, 233 (CCPA 1964); In re Walters, 168 f.2d 79, 80, 77 USPQ 609, 610 (CCPA 1948); et al.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. In re McLaughlin, 443 F.2d 1392; 170 USPQ 209 (CCPA 1971).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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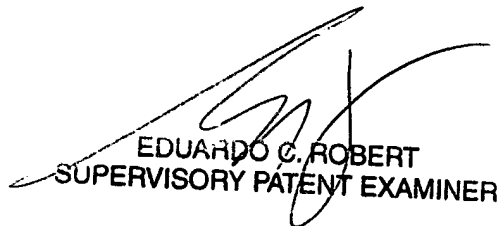
mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette R. Reimers whose telephone number is (571) 272-7135. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AR



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER